

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I given ISTODAX?

ISTODAX contains the active ingredient romidepsin. ISTODAX is used to treat a type of cancer called peripheral T-cell lymphoma, or PTCL, in patients who have received at least one previous treatment for this condition.

For more information, see Section [1. Why am I given ISTODAX?](#) in the full CMI.

2. What should I know before I am given ISTODAX?

Do not use if you have ever had an allergic reaction to romidepsin or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I am given ISTODAX?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with ISTODAX and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How am I given ISTODAX?

- ISTODAX will be given to you as an intravenous (IV) infusion into your vein by your doctor or nurse.
- Your doctor will choose the correct dose of ISTODAX for you.

More instructions can be found in Section [4. How am I given ISTODAX?](#) in the full CMI.

5. What should I know while using ISTODAX?

| | |
|----------------------------------|---|
| Things you should do | <ul style="list-style-type: none">• Remind any doctor, dentist, pharmacist, nurses or healthcare professionals you visit that you are using ISTODAX.• Tell all doctors, dentists, and pharmacists who are treating you that you are being given ISTODAX.• If you are going to have surgery, tell the surgeon or anaesthetist that you are being given ISTODAX.• Drink plenty of fluid while taking ISTODAX.• Keep all of your doctor's appointments so that your progress can be checked. |
| Driving or using machines | <ul style="list-style-type: none">• ISTODAX may cause tiredness or the feeling of weakness in some people. If you have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous. |

For more information, see Section [5. What should I know while receiving ISTODAX?](#) in the full CMI.

6. Are there any side effects?

Like all medicines, ISTODAX can cause side effects. Your doctor will discuss potential side effects with you and will explain the risks and benefits of your treatment. Some side effects can be serious and you may require medical attention. Contact your doctor immediately or go to the Emergency Department at your nearest hospital if you have any signs or symptoms (changes to your normal self), particularly if they are getting worse or do not go away.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

ISTODAX[®]

(ISS toe dax)

Active ingredient(s): romidepsin (roe" mi dep' sin)

Consumer Medicine Information (CMI)

This leaflet provides important information about using ISTODAX. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using ISTODAX.**

Where to find information in this leaflet:

1. [Why am I given ISTODAX?](#)
2. [What should I know before I am given ISTODAX?](#)
3. [What if I am taking other medicines?](#)
4. [How am I given ISTODAX?](#)
5. [What should I know while receiving ISTODAX?](#)
6. [Are there any side effects?](#)
7. [Product details](#)

1. Why am I given ISTODAX?

ISTODAX contains the active ingredient romidepsin. ISTODAX is a type of anti-cancer medicine that belongs to a group of medicines known as histone deacetylase or HDAC inhibitors.

ISTODAX is used to treat a type of cancer called peripheral T-cell lymphoma, or PTCL, in patients who have received at least one previous treatment for this condition.

PTCL is a disease in which a type of white blood cell from your immune system, called T-cells, grows abnormally. ISTODAX works by slowing or stopping the growth of these cancer cells. This medicine has also been shown to kill cancer cells.

2. What should I know before I am given ISTODAX?

Warnings

Do not use ISTODAX if:

- you are allergic to romidepsin, or any of the ingredients listed at the end of this leaflet.
- Always check the ingredients to make sure you can use this medicine.

Some of the symptoms of an allergic reaction may include:

- shortness of breath
- wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin

Check with your doctor if you:

- have allergies to any other medicines, foods, preservatives or dyes.
- have a history of heart problems or are taking medicines used to help treat abnormal rhythms of the heart (anti-arrhythmics).

ISTODAX treatment has been associated with the occurrence of abnormal heart rhythms. Your doctor may conduct a heart function (electrocardiograph [ECG]) test before and during treatment to monitor the activity of your heart.

- have a history of blood conditions which affect the number of blood cells in your body.

This medicine can cause a reduction in the numbers of blood cells. Your doctor will ask you to take regular blood tests to monitor the levels of your blood cells.

- have a history of frequent infections, or a history of hepatitis B or Epstein Barr virus infection.

This medicine can cause a reduction in the numbers of blood cells used by the body to fight infection. Your doctor will ask you to take regular blood tests to monitor the levels of your blood cells.

- are pregnant or plan to become pregnant.

ISTODAX can harm your unborn baby. Your doctor will ask you to have a pregnancy test prior to starting treatment with ISTODAX. Your doctor can discuss with you the risks and benefits of using this medicine during pregnancy.

- use reliable means of contraception during treatment and treatment interruptions, and for at least 4 weeks after ISTODAX treatment has stopped.

Your doctor will tell you what method of contraception to use.

- are breast-feeding or plan to breast-feed.

It is not known if ISTODAX passes into breast milk. Your doctor will help to decide if you should stop breast-feeding when you start treatment with this medicine.

- have a history of kidney problems.
- have problems with the amount of potassium or magnesium in your blood.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section 6. [Are there any side effects?](#)

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

ISTODAX is not recommended for use in pregnant women. ISTODAX can harm your unborn baby. Your doctor will ask

you to have a pregnancy test prior to starting treatment with ISTODAX. Your doctor can discuss with you the risks and benefits of using this medicine during pregnancy.

Use reliable means of contraception during treatment and treatment interruptions, and for at least 4 weeks after ISTODAX treatment has stopped. Your doctor will tell you what method of contraception to use.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

It is not known if ISTODAX passes into breast milk. Your doctor will help to decide if you should stop breast-feeding when you start treatment with this medicine.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines may interfere with each other. These include:

- warfarin or any other blood thinner used to prevent blood clots
- medicines used to treat heart problems such as arrhythmia (irregular beating of the heart)
- medicines used to treat fungal infections (such as ketoconazole)
- medicines used to treat tuberculosis (such as rifampin)
- oestrogen-containing oral contraceptive pills for women
- St John's Wort.

These medicines may be affected by ISTODAX or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking ISTODAX.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect ISTODAX.

4. How am I given ISTODAX?

How is ISTODAX given

ISTODAX will be given to you as an intravenous (IV) infusion into your vein by your doctor or nurse.

Your doctor will choose the correct dose of ISTODAX for you.

Your dose will depend on your general condition and your height and weight.

Your dose will be calculated based on your body surface area, with the usual dose of 14 mg ISTODAX per metre squared of body surface area.

ISTODAX will be given to you over a 4-hour period on Days 1, 8 and 15 of a 28-day cycle. These cycles may be

repeated for as long as you continue to receive benefit from ISTODAX.

Your doctor will check your progress and may change your dose if necessary.

Your doctor may also give you another medicine to help stop you feeling sick (nausea) and vomiting.

If you have any questions on the use of ISTODAX, ask your doctor.

If you miss a dose of ISTODAX

It is very important for you to keep all appointments to receive ISTODAX. If you miss an appointment, ask your doctor when to schedule your next dose.

If you are given too much ISTODAX

As ISTODAX is given to you under the supervision of your doctor, it is unlikely that you will be given too much.

However, if you experience any side effects after being given ISTODAX, tell your doctor immediately.

5. What should I know while receiving ISTODAX?

Things you should do

Tell all doctors, dentists, pharmacists, nurses or healthcare professionals who are treating you that you are being given ISTODAX.

If you are going to have surgery, tell the surgeon or anaesthetist that you are being given ISTODAX.

It may affect other medicines used during or after the surgery.

Drink plenty of fluid while taking ISTODAX. Discuss with your doctor how much water you should drink.

Having enough fluids may help to reduce the chances of dehydration.

Keep all of your doctor's appointments so that your progress can be checked.

Your doctor will need to perform regular ECG (heart function) tests and blood tests.

Call your doctor straight away if you:

- become pregnant while being given ISTODAX.

Remind any doctor, dentist, pharmacist, nurses or healthcare professionals you visit that you are using ISTODAX.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how ISTODAX affects you.

ISTODAX may cause tiredness or the feeling of weakness in some people. If you have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Serious side effects

| Serious side effects | What to do |
|--|--|
| <ul style="list-style-type: none"> Sudden signs of allergy such as rash, itching or hives on the skin; swelling of the face, lips or tongue or other parts of the body; and/or shortness of breath, wheezing or trouble breathing. <p>You may have a low number of white blood cells that fight infection. Patients receiving ISTODAX can develop serious infections that sometimes lead to death.</p> | <p>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</p> |
| <ul style="list-style-type: none"> Symptoms of infection such as fever, chills, sore throat, cough, shortness of breath with or without chest pain, mouth ulcers, burning with urination, flu-like symptoms or any other sign of infection. | |
| <ul style="list-style-type: none"> Abnormal heart-beat, or feeling dizzy or faint. <p>This could be due to a change in your heart-rate and/or low levels of potassium or magnesium in your blood.</p> | |
| <ul style="list-style-type: none"> Sudden pain in your chest or difficulty in breathing. <p>This may be due to blood clots in the artery leading to your lungs.</p> | |
| <ul style="list-style-type: none"> Pain or swelling in your legs, especially in your lower leg or calves. <p>This may be due to blood clots in the veins of your leg.</p> | |
| <ul style="list-style-type: none"> Heavy bleeding in the absence of injury. | |

| Serious side effects | What to do |
|--|------------|
| <p>You may have a very low number of platelets, which are the blood cells that help to clot your blood.</p> <ul style="list-style-type: none"> Racing heart, extreme fatigue, headaches. <p>You may have a very low number of red blood cells that carry oxygen.</p> | |

Other side effects

| Common side effects | What to do |
|---|--|
| <ul style="list-style-type: none"> gastro-intestinal problems such as nausea, vomiting, diarrhoea, constipation, stomach pain, indigestion, a loss of appetite, weight loss, or changes in taste. easy bleeding or bruising in the absence of injury. You may have a low number of platelets, which are the blood cells that help to clot your blood. weakness, tiredness, dizziness, shortness of breath or pale colour. You may have a low number of red blood cells that carry oxygen. swelling of hands, ankles or feet; muscle pain or spasms. signs of dehydration such as dry mouth, increasing thirst, weakness or light-headedness. | <p>Speak to your doctor if you have any of these side effects and they worry you.</p> |

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What ISTODAX contains

| | |
|--|------------|
| Active ingredient (main ingredient) | romidepsin |
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| | |
|---|--|
| Other ingredients (inactive ingredients) | Povidone |
| Solvent | Propylene glycol Anhydrous ethanol |
| Potential allergens | Does not contain lactose, sucrose, gluten, tartrazine or any other azo dyes. |

Do not take this medicine if you are allergic to any of these ingredients.

What ISTODAX looks like

ISTODAX is supplied as a dual pack with one vial containing the white to off-white Istdox powder and the other vial containing a clear solvent.

Registration Numbers

ISTODAX (romidepsin) 10mg powder for injection vial and solvent for reconstitution vial (AUST R 198854)

Who distributes ISTODAX

Bristol-Myers Squibb Australia Pty Ltd

4 Nexus Court, Mulgrave

Victoria 3170, Australia

Toll free number: 1800 067 567

Email: MedInfo.Australia@bms.com

ISTODAX® is a trademark of Celgene Corporation, a Bristol Myers Squibb Company

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